

108TH CONGRESS
1ST SESSION

H. R. 2544

To improve the quality, availability, diversity, personal privacy, and innovation of health care in the United States.

IN THE HOUSE OF REPRESENTATIVES

JUNE 19, 2003

Mr. ROHRBACHER introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committees on Energy and Commerce, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To improve the quality, availability, diversity, personal privacy, and innovation of health care in the United States.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medical Independence, Privacy, and Innovation Act of
6 2003”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—TAX-RELATED PROVISIONS

- Sec. 101. Findings.
 Sec. 102. Deduction of medical expenses for individuals.
 Sec. 103. Medical checking accounts.
 Sec. 104. Decrease in minimum annual deductibles under a high deductible health plan for purposes of Archer MSAs.

TITLE II—MEDICAL PRIVACY

- Sec. 201. Findings.
 Sec. 202. Modification of regulations on privacy of individually identifiable health information.

TITLE III—MODIFICATIONS REGARDING REGULATION OF DRUGS
UNDER FEDERAL FOOD, DRUG, AND COSMETIC ACT

- Sec. 301. Definition of drug.
 Sec. 302. Striking of effectiveness requirement; modifications regarding patent listings, patent certifications, and thirty-month rule.
 Sec. 303. Granting of exclusive or partially exclusive licenses regarding inventions made with Federal assistance.
 Sec. 304. Importation of certain drugs.

1 **TITLE I—TAX-RELATED**
 2 **PROVISIONS**

3 **SEC. 101. FINDINGS.**

4 The Congress finds the following:

5 (1) Current law confers tax benefits for health
 6 insurance provided as an employee fringe benefit,
 7 but no similar tax benefit for health insurance pur-
 8 chased by individuals thus creating an unfair bias
 9 toward employer provided medical insurance plans
 10 and an unfair discrimination against individuals who
 11 seek marketplace alternatives to health insurance.

12 (2) Current law confers a tax benefits for third
 13 party payment of medical expenses but no similar
 14 tax benefits for direct individual payment of medical
 15 expenses. This has promoted employer-provided

1 third party payment systems and discouraged direct
2 doctor-patient relationships.

3 (3) The current tax treatment of medical ex-
4 penses has resulted in a greatly distorted market-
5 place in medical insurance where decreased opportu-
6 nities for private personal health insurance has re-
7 duced competition both for medical insurance and
8 health care services. This has resulted in an in-
9 creased costs of both health insurance and health
10 care services and fostered over use of low high pre-
11 mium health insurance plans.

12 (4) The current tax treatment of medical ex-
13 penses has restricted the freedom of individuals to
14 exercise direct control over their health care dollars.
15 The exclusion from gross income for employer-pro-
16 vided health care with no corresponding tax benefit
17 for health insurance and health care costs bourn by
18 individuals represents a strong incentive toward em-
19 ployers group plans.

20 (5) The tax codes preferment of employer-pro-
21 vided group plans has triggered a marketplace re-
22 sponse reflected in the significant increases in large
23 health care delivery, and the creation of a relative
24 few health care conglomerates in lieu of thousands
25 of competitive providers of medical insurance and

1 services. This has increasingly placed medical deci-
 2 sions in the hands of health care bureaucracies and
 3 has eroded doctor-patient relationships.

4 (6) The role of the marketplace in both medical
 5 insurance and medical services should be strength-
 6 ened. The discriminatory tax policies in the area of
 7 health insurance and health care should be ended.
 8 Private individuals should be able to contract for
 9 their health insurance and health care delivery in at-
 10 mosphere free of discriminatory tax pressures. High
 11 deductible low premium as well as catastrophic alter-
 12 natives in health insurance should be viable options
 13 for all Americans.

14 **SEC. 102. DEDUCTION OF MEDICAL EXPENSES FOR INDIVIDUALS.**
 15 **VIDUALS.**

16 (a) IN GENERAL.—Subsection (a) of section 213 of
 17 the Internal Revenue Code of 1986 (relating to treatment
 18 of medical, dental, etc., expenses) is amended to read as
 19 follows:

20 “(a) ALLOWANCE OF DEDUCTION.—There shall be
 21 allowed as a deduction the expenses paid during the tax-
 22 able year, not compensated for by insurance or otherwise,
 23 for medical care of the taxpayer, his spouse, or a depend-
 24 ent (as defined by section 152).”.

1 (b) DEDUCTION ALLOWED IN COMPUTING AD-
2 JUSTED GROSS INCOME.—Subsection (a) of section 62 of
3 such Code is amended by inserting after paragraph (18)
4 the following new paragraph:

5 “(19) MEDICAL CARE.—The deduction allowed
6 by section 213.”.

7 (c) CONFORMING AMENDMENTS.—

8 (1) Section 56(b)(1) of such Code is amended
9 by striking subparagraph (B).

10 (2) Section 67(b) is amended by striking para-
11 graph (5).

12 (3) Section 72(t)(B) of such Code is amended
13 by striking “to the extent such distributions do not
14 exceed the amount” and inserting “which are”.

15 (4) Sections 104(a) and 105(b) of such Code
16 are both amended by striking “(and not in excess
17 of)”.

18 (d) EFFECTIVE DATE.— The amendments made by
19 this section shall apply to taxable years beginning after
20 December 31, 2003.

21 **SEC. 103. MEDICAL CHECKING ACCOUNTS.**

22 (a) IN GENERAL.—Subchapter F of chapter 1 of the
23 Internal Revenue Code of 1986 (relating to exempt organi-
24 zations) is amended by adding at the end the following:

1 **“PART IX—MEDICAL CHECKING ACCOUNTS**

“Sec. 530A. Medical checking accounts.

2 **“SEC. 530A. MEDICAL CHECKING ACCOUNTS.**

3 “(a) GENERAL RULE.—A medical checking account
4 shall be exempt from taxation under this subtitle. Not-
5 withstanding the preceding sentence, any medical checking
6 account shall be subject to the taxes imposed by section
7 511 (relating to imposition of tax on unrelated business
8 income of charitable, etc., organizations). Rules similar to
9 the rules of paragraphs (2) and (4) of section 408(e) shall
10 apply to medical checking accounts, and any amount treat-
11 ed as distributed under such rules shall be treated as not
12 used to pay qualified medical expenses.

13 “(b) DEDUCTION FOR CONTRIBUTIONS.—

14 “(1) IN GENERAL.—In the case of an indi-
15 vidual, there shall be allowed as a deduction an
16 amount equal to the aggregate amount paid in cash
17 during the taxable year to a medical checking ac-
18 count of the taxpayer.

19 “(2) LIMITATIONS.—

20 “(A) MAXIMUM ANNUAL CONTRIBUTION.—

21 The deduction under paragraph (1) for a tax-
22 able year shall not exceed \$1,000 (\$2,000 in
23 the case of a joint return).

24 “(B) MAXIMUM ALLOWABLE DEDUCTION
25 BASED ON BALANCE IN ACCOUNT.—No deduc-

tion shall be allowed for a taxable year for any amount contributed to a medical checking account if the sum of such amount plus the balance in the account determined as the end of the taxable year would exceed \$2,000 (\$4,000 in the case of married individuals filing a joint return, a surviving spouse, and a head of household).

“(c) CREDIT FOR CONTRIBUTIONS.—

“(1) IN GENERAL.—In the case of an individual, there shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to the credit amount with respect to contributions made during the taxable year to the medical checking account of the taxpayer.

“(2) CREDIT AMOUNT.—For purposes of paragraph (1), the credit amount is the lesser of—

“(A) the total amount of contributions to the medical checking account for the taxable year reduced by the amount of contributions allowed as a deduction under subsection (b), and

“(B) \$1,000.

“(d) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

1 “(1) MEDICAL CHECKING ACCOUNT.—The term
2 ‘medical checking account’ means a trust created or
3 organized in the United States for the exclusive ben-
4 efit of a qualified individual or his beneficiaries, but
5 only if the written governing instrument creating the
6 trust meets the following requirements:

7 “(A) Except in the case of a rollover con-
8 tribution described in paragraph (4)(C), no con-
9 tribution will be accepted unless it is in cash, or
10 it exceeds \$1,000 (\$2,000 in the case of mar-
11 ried individuals filing a joint return, a surviving
12 spouse, and a head of household).

13 “(B) The trustee is a bank (as defined in
14 section 408(n), an insurance company (as de-
15 fined in section 816), or another person who
16 demonstrates to the satisfaction of the Sec-
17 retary that the manner in which such person
18 will administer the trust will be consistent with
19 the requirements of this section.

20 “(C) No part of the trust assets will be in-
21 vested in life insurance contracts.

22 “(D) The assets of the trust will not be
23 commingled with other property except in a
24 common trust fund or common investment
25 fund.

1 “(E) The interest of an individual in the
2 balance in his account is nonforfeitable.

3 “(2) QUALIFIED MEDICAL EXPENSES.—The
4 term ‘qualified medical expenses’ means, with re-
5 spect to an account holder, amounts paid by such
6 holder for medical care (as defined in section 213(d)
7 for such individual, the spouse of such individual,
8 and any dependent (as defined in section 152 of
9 such individual, but only to the extent such amounts
10 are not compensated for by insurance or otherwise
11 (including distributions from an Archer MSA which
12 are not includible in gross income by reason of sec-
13 tion 220(f)(1)).

14 “(3) CHANGE IN FILING STATUS.—In the case
15 of a taxpayer whose filing status changes during the
16 taxable year, the limitation under subparagraph (B)
17 shall be apportioned among the filing statuses of the
18 taxpayer in accordance with regulations prescribed
19 by the Secretary.

20 “(4) CERTAIN RULES TO APPLY.—Rules similar
21 to the following rules shall apply for purposes of this
22 section:

23 “(A) Section 219(d)(2) (relating to no de-
24 duction for rollovers).

1 “(B) Section 219(f)(3) (relating to time
2 when contributions deemed made).

3 “(C) Section 219(f)(5) (relating to em-
4 ployer payments).

5 “(D) Section 220(f)(5) (relating to rollover
6 contributions).

7 “(E) Section 220(f)(7) (relating to trans-
8 fer of account incident to divorce).

9 “(F) Section 220(f)(8) (relating to treat-
10 ment after death of account holder).

11 “(G) Section 408(g) (relating to commu-
12 nity property laws).

13 “(H) Section 408(h) (relating to custodial
14 accounts).

15 “(e) TAX TREATMENT OF DISTRIBUTIONS.—

16 “(1) AMOUNTS USED FOR QUALIFIED MEDICAL
17 EXPENSES.—Any amount paid or distributed out of
18 a medical checking account which is used exclusively
19 to pay qualified medical expenses of any account
20 holder shall not be includible in gross income.

21 “(2) INCLUSION OF AMOUNTS NOT USED FOR
22 QUALIFIED MEDICAL EXPENSES.—Any amount paid
23 or distributed out of a medical checking account
24 which is not used exclusively to pay the qualified

1 medical expenses of the account holder shall be in-
2 cluded in the gross income of such holder.

3 “(3) ADDITIONAL TAX ON DISTRIBUTIONS NOT
4 USED FOR QUALIFIED MEDICAL EXPENSES.—For
5 purposes of this section, rules similar to the rules of
6 section 220(f)(4) shall apply.

7 “(4) COORDINATION WITH MEDICAL EXPENSE
8 DEDUCTION.—For purposes of determining the
9 amount of the deduction under section 213, any pay-
10 ment or distribution out of a medical checking ac-
11 count for qualified medical expenses shall not be
12 treated as an expense paid for medical care.

13 “(f) REPORTS.—The Secretary may require the
14 trustee of a medical checking account to make such re-
15 ports regarding such account to the Secretary and to the
16 account holder with respect to contributions, distributions,
17 and such other matters as the Secretary determines appro-
18 priate. The reports required by this subsection shall be
19 filed at such time and in such manner and furnished to
20 such individuals at such time and in such manner as may
21 be required by the Secretary.”.

22 (b) TAX ON EXCESS CONTRIBUTIONS.—Section 4973
23 of such Code (relating to tax on excess contributions to
24 individual retirement accounts, certain section 403(b) con-

1 tracts, and certain individual retirement annuities) is
2 amended—

3 (1) in subsection (a) by striking “or” at the end
4 of paragraph (3), by inserting “or” at the end of
5 paragraph (4), and by inserting after paragraph (4)
6 the following:

7 “(5) a medical checking account (within the
8 meaning of section 530A(d)),”, and

9 (2) by adding at the end the following new sub-
10 section:

11 “(g) EXCESS CONTRIBUTIONS TO MEDICAL CHECK-
12 ING ACCOUNTS.—For purposes of this section, in the case
13 of medical checking accounts (within the meaning of sec-
14 tion 530A(d)), the term ‘excess contributions’ means the
15 sum of—

16 “(1) the aggregate amount contributed for the
17 taxable year to the accounts (other than rollover
18 contributions referred to in section 530A(d)(4)(C))
19 which is neither excludable from gross income under
20 section 106(b) nor allowable as a deduction or credit
21 under section 530A for such year, and

22 “(2) the amount determined under this sub-
23 section for the preceding taxable year, reduced by
24 the sum of—

1 “(A) the distributions out of the accounts
 2 which were included in gross income under sec-
 3 tion 530A(e)(2), and

4 “(B) the excess (if any) of—

5 “(i) the sum of the maximum amount
 6 allowable as a deduction or credit under
 7 section 530A (determined without regard
 8 to section 106(b)) for the taxable year,
 9 over

10 “(ii) the amount contributed to the
 11 accounts for the taxable year.

12 For purposes of this subsection, any contribution which
 13 is distributed out of the medical savings account in a dis-
 14 tribution to which section 530A(d)(4)(B) applies shall be
 15 treated as an amount not contributed.”.

16 (c) TAX ON PROHIBITED TRANSACTIONS.—

17 (1) Section 4975 of such Code (relating to tax
 18 on prohibited transactions) is amended by adding at
 19 the end of subsection (c) the following new para-
 20 graph:

21 “(6) SPECIAL RULE FOR MEDICAL CHECKING
 22 ACCOUNTS.—An individual for whose benefit a med-
 23 ical checking account (within the meaning of section
 24 530A(d)) is established shall be exempt from the tax
 25 imposed by this section with respect to any trans-

1 action concerning such account (which would other-
 2 wise be taxable under this section) if, with respect
 3 to such transaction, the account ceases to be a med-
 4 ical checking account by reason of the application of
 5 section 530A(e)(2) to such account.”.

6 (2) Paragraph (1) of section 4975(e) of such
 7 Code is amended by striking “or” at the end of sub-
 8 paragraph (E), by redesignating subparagraph (F)
 9 as subparagraph (G), and by inserting after sub-
 10 paragraph (E) the following new subparagraph:

11 “(F) a medical checking account described
 12 in section 530A(d), or”.

13 (d) FAILURE TO PROVIDE REPORTS ON MEDICAL
 14 CHECKING ACCOUNTS.—Paragraph (2) of section 6693(a)
 15 (relating to general rule on reports) is amended by strik-
 16 ing “and” at the end of subparagraph (C), by striking the
 17 period at the end of subparagraph (D) and inserting “,
 18 and”, and by inserting after subparagraph (D) the fol-
 19 lowing new subparagraph:

20 “(E) section 530A(g) (relating to medical
 21 savings accounts).”.

22 (e) CLERICAL AMENDMENT.—The table of parts for
 23 subchapter F of chapter 1 of such Code is amended by
 24 adding at the end the following new item:

“PART IX. MEDICAL CHECKING ACCOUNTS.”.

1 (f) EFFECTIVE DATE.—The amendments made by
 2 this section shall apply to taxable years beginning after
 3 December 31, 2003.

4 **SEC. 104. DECREASE IN MINIMUM ANNUAL DEDUCTIBLES**
 5 **UNDER A HIGH DEDUCTIBLE HEALTH PLAN**
 6 **FOR PURPOSES OF ARCHER MSAS.**

7 (a) IN GENERAL.—Subparagraph (A) of section
 8 220(c)(2) of the Internal Revenue Code of 1986 (defining
 9 high deductible health plan) is amended—

10 (1) in clause (i) by striking “\$1,500” and in-
 11 serting “\$1,000”, and

12 (2) in clause (ii) by striking “\$3,000” and in-
 13 serting “\$2,000”.

14 (b) MINIMUM NOT INCREASED BY INFLATION.—Sec-
 15 tion 220(g) of such Code is amended by inserting “(other
 16 than the \$1,000 amount in subparagraph (A)(i) and the
 17 \$2,000 amount in subparagraph (A)(ii) thereof)” after
 18 “subsection (c)(2)”.

19 (c) EFFECTIVE DATE.—The amendments made by
 20 this section shall apply to taxable years beginning after
 21 December 31, 2003.

22 **TITLE II—MEDICAL PRIVACY**

23 **SEC. 201. FINDINGS.**

24 The Congress finds the following:

1 (1) Medical privacy is an issue that concerns a
2 growing number of people in the United States. The
3 culture of the United States has always strongly fa-
4 vored a close physician-patient relationship. One of
5 the key elements of this relationship is the trust that
6 a patient has that their personal information will be
7 treated as confidential by medical personnel and will
8 not be made public or accessible to other persons
9 without their permission.

10 (2) In our increasingly complex times, two
11 trends are combining to exert pressure on maintain-
12 ing the confidentiality of health care information.
13 First, public policy favors an increased ability to
14 provide protection against harmful prescription
15 interactions and for the reporting of medications' se-
16 rious side effects. Second, health care insurers desire
17 to take advantage of economies of scale in control-
18 ling health care costs. These trends have greatly re-
19 duced expectations for the privacy of health care in-
20 formation.

21 (3) For the first time in our Nation's history,
22 serious loopholes have been written into privacy pro-
23 tections that were created to protect the right of in-
24 dividuals. Positive changes in privacy law have been
25 made in recent years to guarantee that patients are

1 notified regarding the use of their health informa-
2 tion, have access to their own medical records, and
3 are able to request corrections of such records.
4 These protections must be maintained and strength-
5 ened.

6 (4) One of the greatest needs in the area of
7 health privacy is to protect individuals against the
8 use of their confidential health information for prof-
9 it-generating consumer marketing. Patients justifi-
10 ably have objections to this use of their information
11 without their consent.

12 (5) There recently have been implemented a se-
13 ries of alarming modifications to the standards pre-
14 viously finalized to protect the privacy of individually
15 identifiable health information. These include
16 changes in important definitions, additions to the
17 category of health care operations for which patient
18 consent for the use of their information is not re-
19 quired, and changes in permitted use of patient in-
20 formation without consent for public health pur-
21 poses.

22 (6) Recent rollbacks in health privacy need to
23 be reversed, and the individuals' confidence that
24 their private conversations with medical personnel
25 will remain private needs to be strengthened.

1 (7) There is also a need to protect the integrity
 2 and confidentiality of social security account num-
 3 bers and to prohibit Federal agencies from imposing
 4 national standards for identification of individuals.

5 **SEC. 202. MODIFICATION OF REGULATIONS ON PRIVACY OF**
 6 **INDIVIDUALLY IDENTIFIABLE HEALTH IN-**
 7 **FORMATION.**

8 (a) MARKETING.—

9 (1) IN GENERAL.—The modifications made by
 10 the August 2002 medical privacy rule to the defini-
 11 tion of the term “marketing” in section 164.501 of
 12 title 45, Code of Federal Regulations, shall have no
 13 force or effect.

14 (2) AUTHORIZATIONS FOR MARKETING.—Sec-
 15 tion 164.508 of title 45, Code of Federal Regula-
 16 tions, shall be construed and applied so as to require
 17 that, if an authorization is required for a use or dis-
 18 closure of protected health information for mar-
 19 keting, the authorization shall be considered invalid
 20 unless it—

21 (A) uses the term “marketing”;

22 (B) states that the purpose of the use or
 23 disclosure involved is marketing; and

24 (C) describes the specific marketing uses
 25 and disclosures authorized.

1 (b) CONSENT FOR USES OR DISCLOSURES TO CARRY
2 OUT TREATMENT, PAYMENT, OR HEALTH CARE OPER-
3 ATIONS.—

4 (1) IN GENERAL.—The modifications made to
5 section 164.506 of title 45, Code of Federal Regula-
6 tions, by the August 2002 medical privacy rule shall
7 have no force or effect.

8 (2) USE OR DISCLOSURE WITHOUT CONSENT.—

9 (A) IN GENERAL.—Section 164.506 of title
10 45, Code of Federal Regulations, insofar as it
11 permits any use or disclosure of protected
12 health information without consent, shall have
13 no force or effect.

14 (B) CIRCUMSTANCES WHERE CONSENT
15 NOT REQUIRED.—A health care provider may
16 use or disclose an individual's protected health
17 information without obtaining the prior consent
18 of the individual only in the following cir-
19 cumstances:

20 (i) To fill or dispense a prescription,
21 and to search for drug interactions related
22 to that prescription, if the health care pro-
23 vider obtains written consent from the in-
24 dividual as soon as practicable.

(ii) To carry out treatment of that individual if—

(I) the individual has not executed a Universal Health Privacy Declaration promulgated under subparagraph (C);

(II) the individual and the health care provider have not had in-person communication regarding such treatment; and

(III) obtaining consent would be impracticable.

(C) UNIVERSAL HEALTH PRIVACY DECLARATION.—

(i) IN GENERAL.—The Secretary of Health and Human Services shall promulgate a document which shall be known as the “Universal Health Privacy Declaration”.

(ii) ELIGIBILITY.—A Universal Health Privacy Declaration may be executed by any individual who is a citizen of the United States or an alien lawfully admitted to the United States for permanent residence.

1 (iii) PURPOSE.—A Universal Health
2 Privacy Declaration, once executed by an
3 individual described in clause (ii) and not
4 revoked, shall be considered to prohibit, as
5 provided under subparagraph (B), a health
6 care provider from using or disclosing the
7 individual’s protected health information
8 for treatment without obtaining the prior
9 consent of the individual.

10 (iv) ENFORCEMENT.—There is estab-
11 lished in the Department of Health and
12 Human Services an Office of the Health
13 Privacy Ombudsman, which shall be head-
14 ed by an individual known as the “Health
15 Privacy Ombudsman”. The Health Privacy
16 Ombudsman shall be charged with inves-
17 tigating complaints submitted by individ-
18 uals described in clause (ii) regarding a
19 use or disclosure of protected health infor-
20 mation in violation of their Universal
21 Health Privacy Declaration.

22 (c) DISCLOSURES FOR LAW ENFORCEMENT PUR-
23 POSES.—Subparagraph (C) of section 164.506(f)(1)(ii) of
24 title 45, Code of Federal Regulations shall have no force
25 or effect.

1 (d) DEFINITIONS.—

2 (1) IN GENERAL.—For purposes of this section:

3 (A) DECEMBER 2000 MEDICAL PRIVACY
4 RULE.—The term “December 2000 medical pri-
5 vacy rule” means the final rule on standards
6 for privacy of individually identifiable health in-
7 formation published on December 28, 2000, in
8 the Federal Register (65 Fed. Reg. 82462), in-
9 cluding the provisions of title 45, Code of Fed-
10 eral Regulations, revised or added by such rule.

11 (B) AUGUST 2002 MEDICAL PRIVACY
12 RULE.—The term “August 2002 medical pri-
13 vacy rule” means the final rule, published on
14 August 14, 2002, in the Federal Register (67
15 Fed. Reg. 53182), that modified the December
16 2000 medical privacy rule.

17 (2) OTHER TERMS DEFINED.—For purposes of
18 this section:

19 (A) HEALTH CARE PROVIDER.—The term
20 “health care provider” shall have the meaning
21 given such term in section 160.103 of title 45,
22 Code of Federal Regulations, as contained in
23 the December 2000 medical privacy rule.

24 (B) DISCLOSURE; INDIVIDUAL; PROTECTED
25 HEALTH INFORMATION; TREATMENT; USE.—

1 The terms “disclosure”, “individual”, “pro-
 2 tected health information”, “treatment”, and
 3 “use” shall have the meaning given such terms
 4 in section 164.501 of title 45, Code of Federal
 5 Regulations, as contained in the December
 6 2000 medical privacy rule.

7 **TITLE III—MODIFICATIONS RE-**
 8 **GARDING REGULATION OF**
 9 **DRUGS UNDER FEDERAL**
 10 **FOOD, DRUG, AND COSMETIC**
 11 **ACT**

12 **SEC. 301. DEFINITION OF DRUG.**

13 Section 201(g)(1) of the Federal Food, Drug, and
 14 Cosmetic Act (21 U.S.C. 321(g)(1)) is amended in the
 15 first sentence by striking “and (B) articles intended” and
 16 all that follows and inserting the following: “and (B) arti-
 17 cles intended for use in the diagnosis, cure, or treatment
 18 (but not mitigation or prevention) of disease in man or
 19 other animals.”.

20 **SEC. 302. STRIKING OF EFFECTIVENESS REQUIREMENT;**
 21 **MODIFICATIONS REGARDING PATENT LIST-**
 22 **INGS, PATENT CERTIFICATIONS, AND THIRTY-**
 23 **MONTH RULE.**

24 (a) STRIKING OF EFFECTIVENESS REQUIREMENT;
 25 PROHIBITION AGAINST LISTING OF CERTAIN PATENTS.—

1 (1) IN GENERAL.—Section 505(b) of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(b)) is amended by striking “(b)(1)” and all that
4 follows through “clinical trials required by clause
5 (A).” and inserting the following:

6 “(b) APPLICATION.—

7 “(1) CONTENTS.—

8 “(A) IN GENERAL.—Any person may file
9 with the Secretary an application with respect
10 to any drug subject to the provisions of sub-
11 section (a). Such persons shall submit to the
12 Secretary as a part of the application—

13 “(i) full reports of investigations
14 which have been made to show whether or
15 not such drug is safe for use;

16 “(ii) a full list of the articles used as
17 components of such drug;

18 “(iii) a full statement of the composi-
19 tion of such drug;

20 “(iv) a full description of the methods
21 used in, and the facilities and controls
22 used for, the manufacture, processing, and
23 packing of such drug;

1 “(v) such samples of such drug and of
2 the articles used as components thereof as
3 the Secretary may require; and

4 “(vi) specimens of the labeling pro-
5 posed to be used for such drug.

6 “(B) PATENT INFORMATION.—

7 “(i) REQUIREMENT.—The applicant
8 shall file with the application the patent
9 number and the expiration date of any pat-
10 ent which claims the drug for which the
11 applicant submitted the application or
12 which claims a method of using such drug
13 and with respect to which a claim of patent
14 infringement could reasonably be asserted
15 if a person not licensed by the owner en-
16 gaged in the manufacture use, or sale of
17 the drug.

18 “(ii) TYPES OF PATENTS.—

19 “(I) PATENTS SUBJECT TO RE-
20 QUIREMENT.—The patents for which
21 information under clause (i) is re-
22 quired to be filed with the Secretary
23 are drug substance (ingredient) pat-
24 ents, drug product (formulation and
25 composition) patents, product by proc-

1 ess patents, and method of use pat-
2 ents.

3 “(II) PROHIBITION REGARDING
4 CERTAIN PATENTS.—Process patents,
5 patents claiming packaging, patents
6 claiming metabolites, and patents
7 claiming intermediates are not patents
8 described in subclause (I), and infor-
9 mation on such patents may not be
10 filed with the Secretary.

11 “(III) PATENT REGARDING DRUG
12 SUBSTANCE.—For patents that claim
13 the drug substance, the applicant
14 shall submit information only on pat-
15 ents that claim the drug substance
16 that is the subject of the pending or
17 approved application or that claim a
18 drug substance that is the same as
19 the active ingredient that is the sub-
20 ject of an approved or pending appli-
21 cation within the meaning of sub-
22 section (j)(2)(A)(ii).

23 “(IV) PATENT REGARDING DRUG
24 PRODUCT.—For patents that claim a
25 drug product, the applicant shall sub-

1 mit information only on those patents
2 that claim a drug product that is the
3 subject of a pending or approved ap-
4 plication.

5 “(V) PATENT REGARDING METH-
6 OD OF USE.—For patents that claim a
7 method of use, the applicant shall
8 submit information only on those pat-
9 ents that claim indications or other
10 conditions of use that are the subject
11 of a pending or approved application.
12 For approved applications, the appli-
13 cant shall identify the indication or
14 other condition of use in the approved
15 labeling that corresponds to the listed
16 patent and claim identified.

17 “(iii) FILING OF PATENT AFTER SUB-
18 MISSION OF APPLICATION.—If an applica-
19 tion is filed under this subsection for a
20 drug and a patent which claims such drug
21 or a method of using such drug is issued
22 after the filing date but before approval of
23 the application, the applicant shall amend
24 the application to include the information
25 required by clauses (i) and (ii).

1 “(iv) PUBLICATION OF PATENT IN-
2 FORMATION.—Upon approval of the appli-
3 cation, the Secretary shall publish informa-
4 tion submitted under clauses (i) through
5 (iii).

6 “(C) GUIDANCE REGARDING INCLUSION OF
7 WOMEN AND MINORITIES IN CLINICAL
8 TRIALS.—The Secretary shall, in consultation
9 with the Director of the National Institutes of
10 Health and with representatives of the drug
11 manufacturing industry, review and develop
12 guidance, as appropriate, on the inclusion of
13 women and minorities in clinical trials required
14 by subparagraph (A)(i).”.

15 (2) CONFORMING AMENDMENTS.—The Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
17 seq.) is amended—

18 (A) in section 201(p)—

19 (i) by striking “safety and effective-
20 ness of” and inserting “safety of”; and

21 (ii) by striking “safe and effective for
22 use” and inserting “safe for use”; and

23 (B) in section 505—

1 (i) by striking “safety and effective-
 2 ness” each place such term appears and
 3 inserting “safety”;

4 (ii) by striking “safety or effective-
 5 ness” each place such term appears and
 6 inserting “safety”; and

7 (iii) in subsection (i)(1)(D), by strik-
 8 ing “pediatric safety and efficacy” and in-
 9 serting “pediatric safety”.

10 (b) ABBREVIATED APPLICATIONS; SINGLE CERTIFI-
 11 CATION REGARDING PATENT INVALIDITY OR NON-
 12 INFRINGEMENT; SINGLE THIRTY-MONTH DELAY IN AP-
 13 PROVAL.—Section 505(j)(2)(A) of the Federal Food,
 14 Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is
 15 amended in the matter after and below clause (viii) by
 16 adding at the end the following sentence: “With respect
 17 to a certification under clause (vii)(IV), an abbreviated ap-
 18 plication (whether or not amended) may not contain more
 19 than one such certification, without regard to patents filed
 20 after the date of the certification.”.

21 **SEC. 303. GRANTING OF EXCLUSIVE OR PARTIALLY EXCLU-**
 22 **SIVE LICENSES REGARDING INVENTIONS**
 23 **MADE WITH FEDERAL ASSISTANCE.**

24 No grant of an exclusive or partially exclusive license
 25 pursuant to chapter 18 of title 35, United States Code,

1 may be made, except in accordance with section 209 of
2 such title (relating to the availability to the public of an
3 invention and its benefits on reasonable terms).

4 **SEC. 304. IMPORTATION OF CERTAIN DRUGS.**

5 Chapter VIII of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 381 et seq.) is amended by striking
7 section 804 and inserting the following:

8 “IMPORTATION OF CERTAIN DRUGS

9 “SEC. 804. (a) REGULATIONS.—The Secretary, after
10 consultation with the United States Trade Representative
11 and the Commissioner of Customs, shall promulgate regu-
12 lations permitting pharmacists and wholesalers to import
13 prescription drugs from foreign nations.

14 “(b) LIMITATION.—The regulations under subsection
15 (a) shall require that safeguards be in place to ensure that
16 each prescription drug imported under the regulations
17 complies with section 505 (including being safe for the in-
18 tended use of the prescription drug) with sections 501 and
19 502 and with other applicable requirements of this Act.”.

○